Non-invasive prospective Pilot in a Live Environment for the Improvement of the diagnosis of skin pathologies in primary care and dermatology - LEGIT.HEALTH_SAN_2024

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000911

Study ID

1000000911

DARWIN EU® study

No

Study countries

Spain

Study description

Title: Non-invasive prospective Pilot in a Live Environment for the Improvement of the diagnosis of skin pathologies in primary care and dermatology

Protocol Code: LEGIT.HEALTH_SAN_2024

Study Design & Objectives

This prospective, observational, cross-sectional validation study evaluated whether the AI-based medical device, Legit.Health Plus (v1.1.0.0) improves diagnostic accuracy for multiple dermatological conditions. The primary objective was to validate that the device increases true diagnostic accuracy among Healthcare Professionals (HCPs). Secondary objectives included validating the potential for reducing referrals and increasing remote case management (teledermatology).

Methods

Sixteen healthcare professionals (10 primary care practitioners, 6 dermatologists) were recruited. Each participant evaluated 29 validated images covering 13 distinct pathologies, including Melanoma, Psoriasis, Dermatitis, Tinea, and Acne. A pre-post design was utilised: HCPs diagnosed cases first without assistance, and subsequently reviewed the AI’s analysis (top 5 diagnoses with confidence levels) to confirm or revise their decision. Participants also assessed if the case required specialist referral or could be managed remotely.

Key Results

Overall diagnostic accuracy significantly increased from 68.08% to 88.78% with the device ($p < 0.0001$).

- Primary Care: Accuracy improved markedly from 62.90% to 89.92% (+27.02%).
- Dermatologists: Accuracy improved from 76.47% to 86.93% (+10.46%).

- Referrals: 58.1% of cases were deemed not to require a specialist referral.
- Remote Management: 55.11% of cases could be effectively handled remotely.

Conclusion
The device significantly enhanced diagnostic accuracy and efficiency across specialties. It demonstrated strong potential for triage, reducing unnecessary referrals, and facilitating remote consultations. No adverse events were reported.

Dates: 01/06/2024 – 10/10/2024

Study status
Finalised

Research institutions and networks

Institutions

AI Labs Group S.L. (Legit.Health)

Spain

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Institution | Non-Pharmaceutical company | Other

Contact details

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Study timelines

Date when funding contract was signed

Planned: 15/05/2024

Actual: 15/05/2024

Study start date

Planned: 01/06/2024

Actual: 01/06/2024

Date of final study report

Planned: 10/10/2024

Actual: 10/10/2024

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Medical device

Study topic, other:

Improvement in the diagnosis of skin conditions in primary care and dermatology with the help of the medical device Legit.Health

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Validation of study variables (exposure outcome covariate)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Prospective, observational, analytical, and cross-sectional validation study. A pre-post design was used where 16 HCPs diagnosed 29 validated images first without assistance, then with AI support (Legit.Health Plus) to assess diagnostic accuracy and referral decisions.

Main study objective:

To validate that the information provided by the Legit.Health Plus medical device increases the true diagnostic accuracy of healthcare professionals (HCPs) in the diagnosis of multiple dermatological conditions.

Secondary objectives included:

Validating the percentage of cases that should be referred to a specialist based on the device's information.

Validating the percentage of cases that could be handled remotely (teledermatology) using the device.

Confirming the perceived clinical utility of the device by specialists.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Ulcer

Urticaria

Seborrhoeic keratosis

Psoriasis

Onychomycosis

Malignant melanoma

Herpes simplex

Granuloma annulare

Dermatitis

Alopecia

Acne

Additional medical condition(s)

Tinea; Nevus

Population studied

Short description of the study population

Study Population and Dataset Description

The study population consisted exclusively of Healthcare Professionals (HCPs) rather than patients. A total of 16 physicians were recruited to validate the

diagnostic accuracy and utility of the medical device. The cohort was stratified by speciality to assess performance across different levels of dermatological expertise, comprising 10 primary care practitioners and 6 dermatologists.

The inclusion criteria required participants to be board-certified primary care practitioners or dermatologists, regardless of their years of professional experience. The study did not place specific emphasis on gender, age, or nationality as primary factors for inclusion, aiming instead for a diverse cohort. There were no specific exclusion criteria for the healthcare professionals; exclusion criteria defined in the protocol applied strictly to the quality of clinical images used in the dataset.

Participants acted as their own control group. Each physician was tasked with evaluating a dataset of 29 validated clinical images representing a diverse range of skin pathologies. These images were previously confirmed by dermatologists and, for skin cancer cases, by anatomical pathology.

The composition of the 29-image dataset evaluated by each participant included the following conditions: Dermatitis (5 images), Nevus (4 images), Melanoma (3 images), Psoriasis (3 images), Alopecia (2 images), Herpes (2 images), Tinea (2 images), Onychomycosis (2 images), Acne (2 images), Urticaria (1 image), Granuloma annulare (1 image), Seborrheic keratosis (1 image), and Pressure ulcer (1 image).

Regarding study adherence, 12 of the 16 participants completed the entire process (reviewing all 29 images). The remaining 4 participants reviewed a partial number of images, specifically 28, 15, 9, and 1, respectively.

Estimated number of subjects

16

Study design details

Setting

Persons: 16 Healthcare Professionals participated, comprising 10 Primary Care Practitioners and 6 Dermatologists. Inclusion criteria required board-certified physicians regardless of professional experience. Place: The study was conducted in a remote setting via a dedicated website. Time Period: The study was conducted from June 01, 2024, to October 10, 2024. Selection: Participants evaluated a dataset of 29 validated images representing diverse skin pathologies (e.g., Melanoma, Psoriasis, Dermatitis), confirmed by dermatologists and anatomical pathology. Arms: The study utilized a single-arm, self-controlled design. Participants acted as their own control group, diagnosing images first without the device (standard clinical practice) and subsequently using the Legit.Health Plus device to confirm or revise the diagnosis.

Comparators

The study did not involve an external control group. A within-subject design was employed where the physicians served as their own control. The comparator was the healthcare professional's initial unassisted diagnosis (standard clinical practice) versus their subsequent diagnosis made with the support of the Legit.Health Plus AI analysis (top 5 diagnoses with confidence levels) for the same set of images.

Outcomes

Primary Outcome: Diagnostic accuracy for multiple dermatological conditions, measured as the percentage of correct diagnoses with and without the device. Secondary Outcomes:

Referral Necessity: Percentage of cases identified as requiring specialist referral.

Remote Management: Percentage of cases identified as suitable for remote handling (teledermatology).

Clinical Utility: User perception measured via a questionnaire (usability, confidence, and utility scores). Impact Assessment: Categorisation of the device's influence as reinforcing, improving, no impact, or negative impact.

Data analysis plan

Analysis was conducted using Python (numpy, pandas) to calculate statistical measures. The primary analysis compared diagnostic accuracy percentages before and after using the device. A McNemar test was performed to evaluate the statistical significance of the difference in accuracy. Results were stratified by speciality (Primary Care vs. Dermatologist) and by pathology.

For secondary objectives, the percentages of cases requiring referral or suitable for remote consultation were calculated and analysed using Pearson's chi-squared test to assess associations. Clinical utility was assessed through average scores from participant questionnaires. P-values < 0.05 were considered significant.

Summary results

Overall diagnostic accuracy significantly increased from 68.08% to 88.78% ($p < 0.0001$) with the use of the device.

Primary Care: Accuracy improved substantially from 62.90% to 89.92% (+27.02%).

Dermatologists: Accuracy improved from 76.47% to 86.93% (+10.46%).

Impact: The device reinforced the diagnosis in 67.83% of cases and improved it

in 20.95%.

Referrals: 58.1% of cases were determined not to need a specialist referral.

Remote Management: 55.11% of cases could be handled remotely.

Clinical Utility: HCPs rated the utility of the data at 7.3/10 and the design/usability at 8/10.

Safety: No adverse events were reported.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Non-interventional study

Published literature

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No